VAMHCS RESEARCH & DEVELOPMENT SERVICE
RDS Process Module

PM-SRS-041

Effective Date: July 2016

REPORTING REQUIREMENTS FOR HUMAN RESEARCH PROTECTIONS EVENTS

Applicable Regulatory Context:

[VHA Handbook 1058.01]:

> This Handbook describes requirements for reporting compliance events in VA research to research review committees, VHA officials, and ORO. These requirements do not alter or replace any additional requirements for reporting such events to other internal or external entities as mandated by law, regulation, policy, or agreement.
>
> Paragraph 6 deals specifically with Human Research.

1. Applicable Events in the VAMHCS Human Research Protections Program (HRPP) must be reported to the IRB, VAMHCS Director and ORO in compliance with VHA Handbook 1058.01, as outlined in the tables below. VAMHCS ACOS/R&D and HARPO must also be notified as outlined in the tables below.

2. The R&D Service/HARPO prepares any written reports from the Director to ORO. VAMHCS templates for memo/letter formats must be followed.

3. VA personnel, including WOC and IPA appointees, must ensure *notification of the IRB as below:*

	Event	Method	Timing	How
1	Local Research Death	**oral** notification of the Institutional Review Board (IRB)	**immediately** upon becoming aware of any local research death that is both unanticipated and related to the research.	• Phone IRB Chair or HRPO Director • Follow IRB procedures (RNI #13) • Notify ACOS/R&D, DACOS/R&D, and HARPO
2		**written** notification of the IRB	within **5 business days** after becoming aware of the death	

	Event	Method	Timing	How
3	Local SAE[1] that is both unanticipated and related to the research	**written** notification of the IRB	within **5 business days** after becoming aware of any local SAE that is both unanticipated and related to the research	• Follow RNI procedures; RNI #13 • Notify ACOS/R&D, DACOS/R&D, and HARPO *(IRB then follows HRPO SOP 024 and other applicable procedures to make applicable determinations)*
4	Serious Problems[2]	**written** notification of the IRB	within **5 business days** after becoming aware of any serious problem that is both unanticipated and related to the research	• Follow RNI procedures; RNI #13 • Notify ACOS/R&D, DACOS/R&D, and HARPO *(IRB then follows HRPO SOP 024 and other applicable procedures to make applicable determinations)*
5	Other AEs, SAEs, and Problems	• **written** notification of the IRB • **oral/written** notification of ISO/PO/HARPO for privacy/info security issues	• As defined in UMB IRB SOPs • As defined in PM 044 for privacy/info security issues	• RNIs and Continuing Review reports ***if*** reporting of the event is required by local UMB IRB SOPs • Follow RNI procedures and UMB IRB SOPs • Follow PM 044 for privacy/info security

[1] **Serious Adverse Event**. A Serious Adverse Event (SAE) is an untoward occurrence in human research that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome.

[2] **Serious Problem**. A serious problem is a problem in human research or research information security that may reasonably be regarded as:
(1) Presenting a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or
(2) Substantively compromising a facility's HRPP or research information security program. NOTE: For examples of possible serious problems, see the ORO SharePoint/Web sites at http://vaww.vha.vaco.portal.va.gov/sites/ORO/RCO/default.aspx and http://www.va.gov/oro/. The first link is to an internal Web site and is not available to the public.

	Event	Method	Timing	How
				issues • Notify HARPO for other significant VA-specific events
6	Any apparent serious or continuing noncompliance with IRB or other human research protection requirements	**written** notification of the IRB	within **5 business days** after becoming aware	• Follow RNI procedures. Choose applicable RNI #. • Notify HARPO • Notify PO if it involves a HIPAA issue *(IRB then follows HRPO SOP 024 and other applicable procedures to make applicable determinations)*
7	Suspensions and Terminations of Research **by VAMHCS entities**	**written** notification of the IRB	**immediately** after becoming aware	• Follow RNI procedures (choose applicable RNI #). Include whether any participants could be harmed by the suspension. • Notify ACOS/R&D, DACOS/R&D, and HARPO *(IRB then follows HRPO SOP 024 and other applicable procedures to make applicable determinations)*
8	Any suspension or termination of VA research by, or at the direction of, any entity **external to VAMHCS**			

4. The IRB must report *to the VAMHCS Director* in writing as below:

	Event	Timing	How – Also Cc
A	Receiving notification of a local research death that is both unanticipated and related to the research	within **2 business days**	• EMAIL to Director with Ccs to ACOS/R&D, DACOS/R&D, HARPO, and R&DC Chair(s) • Follow HRPO SOP 024 and other applicable procedures
B	When it reaches determinations regarding a local research death	within **5 business days** of the determinations	• EMAIL to Director with Ccs to ACOS/R&D,

	Event	Timing	How – Also Cc
	(Row A), including elimination of apparent immediate hazards, relatedness to the research, whether it is unanticipated, whether IC or other modifications are required, and whether re-consent is required.		DACOS/R&D, HARPO, and R&DC Chair(s)
C	When it reaches determinations regarding an SAE or serious problem under #3 or #4 above.	within **5 business days** of the convened meeting ***if***: a) actions were taken to eliminate apparent immediate hazards to subjects; or b) the IRB determined that the incident was serious and unanticipated and related to the research, or c) protocol or informed consent modifications were warranted	• EMAIL to Director with Ccs to ACOS/R&D, DACOS/R&D, HARPO, and R&DC Chair(s)
D	When it determines that serious or continuing noncompliance occurred	within **5 business days** of the convened meeting	• EMAIL to Director with Ccs to ACOS/R&D, DACOS/R&D, HARPO, and R&DC Chair(s)
E	Line 7 or 8 above: If it determines that the l study suspensions resulted from local issues (serious or continuing noncompliance, problems or adverse events) or requires local actions to ensure the safety, rights, or welfare of local human research subjects, personnel, or others or the effectiveness of the VAMHCS HRPP	within **5 business days** of determinations	• EMAIL to Director with Ccs to ACOS/R&D, DACOS/R&D, HARPO, and R&DC Chair(s)

5. VAMHCS MCD must report *to ORO* in writing as below:

Event	Timing	How – Also Cc
Items A-E above	within **5 business days** after receiving the IRB's notification	• HARPO prepares letter or memorandum and submits to Executive Suite for review and signature. • Encrypted email sent to ORO HRP Workgroup: orohrp@va.gov with Ccs to COS, ACOS/R&D, DACOS, RCO, VISN 5 Action Group.
Any proposed changes to the FWA, including changes in designated IRB(s) and changes in IRB membership, NOTE: VAMHCS does not need to report Central IRB membership changes to ORO.	**Prior to submission to the Office for Human Research Protections (OHRP)**.	• HARPO sends proposed changes to ORO CO, then proceeds with required changes.
Any change in the status (e.g., expiration, restriction, suspension, or termination) of the facility's Federalwide Assurance (FWA)	within **5 business days** e	• HARPO prepares letter or memorandum and submits to Executive Suite for review and signature. • Encrypted email sent to ORO with Ccs to COS, ACOS/R&D, DACOS, RCO, VISN 5 Action Group.
Failure to achieve or maintain the HRPP accreditation required under VHA Handbook 1200.05		
New or substantially revised MOUs related to human research protections or oversight	within **5 business days** after the final concurrence/signature.	• DACOS sends proposed changes to ORO CO, then proceeds with required changes.

VAMHCS RESEARCH & DEVELOPMENT SERVICE
RDS Process Module

Version	1.1	Origin: 1.0	
Author	Jessica Mendoza		
Changes	• Simplification to table format • Updates/fine-tuning	New Version #	1.1
Approved	Thomas J. Hornyak, ACOS/R&D Date: 3/29/16		
File Name	\041-PM-RDS/HRP-041 Reporting Requirements-HRPP 072616		